



Dkt. 0575/61238-10 JPW/B08

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Richard Deckelbaum et al.
U.S. Serial No. : 10/033,629 Examiner: R. A. Davis
Filed : December 28, 2001 Group Art Unit: 1651
For : USE OF IV EMULSIONS WITH DIFFERENT
TRIGLYCERIDE COMPOSITION, PARTICLE SIZE
AND APOLIPOPROTEIN E FOR TARGETED TISSUE
DELIVERY OF HYDROPHOBIC COMPOUNDS

1185 Avenue of the Americas
New York, New York 10036
March 25, 2003

Assistant Commissioner for Patents
Washington, D.C. 20231

SIR:

COMMUNICATION IN RESPONSE TO FEBRUARY 25, 2002 OFFICE ACTION

This Communication is submitted in response to a February 25, 2003 Office Action issued in connection with the above-identified application. A response to the February 25, 2003 Office Action is due March 25, 2003. Accordingly, this response is being timely filed.

Restriction Requirement Under 35 U.S.C. §121

The Examiner stated that restriction to one of the following allegedly independent and distinct inventions is required under 35 U.S.C. §121:

- I. Claims 1-11, 15-17 and 24-25, drawn to a composition, classified in class 424, subclass 523, for example.
- II. Claims 12-14 and 18-23, drawn to a method for delivering pharmaceutical agents, classified in class 424, subclass 130.1, for

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example.

III. Claims 26-30, drawn to a method for making a composition, classified in class 424, subclass 400, for example.

The Examiner stated that the inventions are distinct, each from the other because of the following reasons:

The Examiner stated that inventions I and II are related as product and process of use. The Examiner stated that the inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP §806.05(h)). The Examiner stated that in the instant case other materially different products could be used to deliver pharmaceutical agents such as polymeric matrices, essential oils or saline solutions.

The Examiner stated that inventions I and III are related as process of making and product made. The Examiner stated that the inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). The Examiner stated that in the instant case the composition could be made by centrifuging or shaking each ingredient together.

In response, applicants note that centrifugation is not materially different from shaking in that both involve admixing ingredients. To the extent the Examiner is in error in this regard all three

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groups of claims should be examined together. See MPEP §806.05(i), a copy of which is attached hereto as **Exhibit A**. Accordingly, applicants request that the Examiner reconsider and withdraw the restriction requirement.

In the February 25, 2003 Office action, the Examiner also stated that the inventions groups II:III are directed to different inventions which are not connected in design, operation, and/or effect. The Examiner stated that these methods are independent since they are not disclosed as capable of use together, they have different modes of operation, they have different functions, and/or they have different effects. The Examiner stated that one would not have to practice the various methods at the same time to practice just one method alone.

The Examiner stated that the several inventions above are independent and distinct, each from the other. The Examiner stated that they have acquired a separate status in the art as a separate subject for inventive effect and require independent searches (as indicated by the different classification). The Examiner stated that the search for each of the above inventions is not co-extensive particularly with regard to the literature search. The Examiner stated that further, a reference which would anticipate the invention of one group would not necessarily anticipate or even make obvious another group.

The Examiner stated that because the inventions are distinct for the reasons given above and the search required for one group is not required for the other groups, restriction for examination

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purposes as indicated is proper.

In response to this restriction requirement, applicants hereby elect, with traverse, to prosecute the invention of Examiner's Group I, drawn to compositions.

Applicants note that 35 U.S.C. §121 states, in part, that "[i]f two or more independent and distinct inventions are claimed in one application, the Commissioner may require application to be restricted to one of the inventions." [Emphasis added]. Applicants request that the restriction requirement be withdrawn in view of the fact that the claims of Groups I-III are not independent.

Under M.P.E.P. §802.1, "independent" means "there is no disclosed relationship between the subjects disclosed, that is, they are unconnected in design, operation, and effect...". The claims of Group I-III are related in that they are drawn to similar compounds, compositions, and methods of use. All of the claims relate to compositions that deliver agents to predefined tissues in a subject.

Applicants therefore respectfully assert that two or more independent and distinct inventions have not been claimed in the subject application because the groups are not independent under M.P.E.P. §802.01. Therefore, restriction is improper under 35 U.S.C. §121.

Additionally, applicants point out that under M.P.E.P. §803, the Examiner must examine the application on the merits, even though it includes claims to distinct inventions, if the search and examination of an application can be made without serious burden.

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There are two criteria for a proper requirement for restriction, namely (1) the invention must be independent and distinct; AND (2) there must be a serious burden on the Examiner if restriction is not required.

Applicants maintain that there would not be a serious burden on the Examiner if restriction were not required. A search of prior art with regard to any of Groups I-III would necessarily identify art for the other Groups. Since there is no serious burden on the Examiner to examine Groups I-III in the subject application, the Examiner must examine the entire application on the merits.

Applicants maintain that claims 1-30 define a single inventive concept. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw the restriction requirement and examine claims 1-30 on the merits.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

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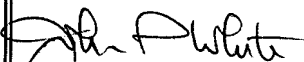
No fee is deemed necessary in connection with the filing of this Communication. If any fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,



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I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231



3/25/03

John P. White
Reg. No. 28,678

Date

3. Conclude restriction requirement with one of form paragraphs 8.21.01 through 8.21.03.

ONLY ONE-WAY DISTINCTNESS IS REQUIRED

The examiner must show by way of example either (A) that the apparatus as *claimed* is not an obvious apparatus for making the product and the apparatus as *claimed* can be used to make other and different products or (B) that the product as *claimed* can be made by another and materially different apparatus.

The burden is on the examiner to provide an example, but the example need not be documented.

If applicant either proves or provides convincing argument that the alternative example suggested by the examiner is not workable, the burden is on the examiner to suggest another viable example or withdraw the restriction requirement.

806.05(h) Product and Process of Using

A product and a process of using the product can be shown to be distinct inventions if either or both of the following can be shown: (A) the process of using as claimed can be practiced with another materially different product; or (B) the product as claimed can be used in a materially different process.

The burden is on the examiner to provide an example, but the example need not be documented.

If the applicant either proves or provides a convincing argument that the alternative use suggested by the examiner cannot be accomplished, the burden is on the examiner to support a viable alternative use or withdraw the requirement.

Form paragraph 8.20 may be used in restriction requirements between the product and method of using.

¶ 8.20 Product and Process of Using

Inventions [1] and [2] are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case [3].

Examiner Note:

1. This form paragraph is to be used when claims are presented to both the **product** and **process of using the product** (MPEP § 806.05(h)).
2. In bracket 3, use one or more of the following reasons:

(a) --the process as claimed can be practiced with another materially different product such as -----

(b) --the product as claimed can be used in a materially different process such as -----

3. Conclude restriction requirement with one of form paragraphs 8.21.01 through 8.21.03.

806.05(i) Product, Process of Making, and Process of Using — Product Claim Not Allowable

37 CFR 1.141. *Different inventions in one national application.*

(b) Where claims to all three categories, product, process of making, and process of use, are included in a national application, a three way requirement for restriction can only be made where the process of making is distinct from the product. If the process of making and the product are not distinct, the process of using may be joined with the claims directed to the product and the process of making the product even though a showing of distinctness between the product and process of using the product can be made.

Where an application contains claims to a product, claims to a process specially adapted for (i.e., not patentably distinct from, as defined in MPEP § 806.05(f)) making the product, and claims to a process of using the product, and the product claims are not allowable (i.e., not novel and nonobvious), restriction is proper between the process of making and the process of using. In this instance, applicant may be required to elect either (A) the product and process of making it; or (B) the process of using. Unless the examiner can make a showing of distinctness between the process of using and the product (MPEP § 806.05(h)), the product must also be joined with the process of using in grouping (B).

Where the product claims are allowable (i.e., novel and nonobvious), restriction may be required only where the process of making and the product made are distinct (MPEP § 806.05(f)); otherwise, the process of using must be joined with the process of making and product made, even if a showing of distinctness can be made between the product and process of using (MPEP § 806.05(h)).

Determination of patentability of the product need not be made prior to making a requirement for restriction unless the requirement is based on a determination that the product claims are not allowable.